The specification of which a. is attached heretob. was filed on

## MERCHANT & GOULD P.C.

## **United States Patent Application**

## COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: CONTROLLED RELEASE PHARMACEUTICAL COMPOSITIONS WITH IMPROVED **BIOAVAILABILITY** 

as (Attorney Docket No. 11336.0033USWO) and as application serial no.

| amended on (if applicab PCT/IB2005/000330 filed 10 F which I solicit a United States I   | ebruary 2005 and as ame  | filed application) of inded on (if                                   | lescribed a<br>any), whicl                | nd claimed in international no.<br>h I have reviewed and for                                 |
|--|--|--|---|--|
| I hereby state that I have review claims, as amended by any ame  |  |  | e-identified                              | d specification, including the   |
| I hereby claim foreign priority I<br>for patent or inventor's certificatinventor's certificate having a fi   | te listed below and have   | also identified belo   | ow any fore                               | eign application for patent or   |
| a. no such applications have b. such applications have b   |  |  |   |  |
| FOREIG   | N APPLICATION(S), IF ANY, CI   | LAIMING PRIORITY UN  | DER 35 USC §                              | 119  |
| COUNTRY  | APPLICATION NUMBER   | DATE OF FILING<br>(day, month, year)                                 |   | DATE OF ISSUE<br>(day, month, year)  |
| Australia  | 2004900661 .   | 11 February 2004   |   | ·  |
| ALL FOREIG   | N APPLICATION(S), IF ANY, FIL  | LED BEFORE THE PRIO  | RITY APPLIC                               | ATION(S)   |
| COUNTRY  | APPLICATION NUMBER   | DATE OF FILING<br>(day, month, year)                                 |   | DATE OF ISSUE<br>(day, month, year)  |
|  |  |  |   |  |
| I hereby claim the benefit under application(s) listed below and, in the prior United States applic § 112, I acknowledge the duty t § 1.56(a) which occurred between this application. | insofar as the subject ma<br>cation in the manner prove<br>to disclose material inform | atter of each of the<br>rided by the first pa<br>mation as defined i | claims of t<br>tragraph of<br>n Title 37, | his application is not disclosed. Title 35, United States Code, Code of Federal Regulations, |
| U.S. APPLICATION NUMBER  | DATE OF FILING (   | day, month, year)  | STATUS                                    | S (patented, pending, abandoned)   |
| hereby claim the benefit under application(s) listed below:  | r Title 35, United States (  | Code § 119(e) of an  | ny United S                               | States provisional   |
| U.S. PROVISIONAL APPI  | DA   | DATE OF FILING (Day, Month, Year)                                    |   |  |

I acknowledge the duty to disclose information that is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (reprinted below):

## § 1.56 Duty to disclose information material to patentability.

- (a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:
  - (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;
- or
  - (2) It refutes, or is inconsistent with, a position the applicant takes in:
    - (i) Opposing an argument of unpatentability relied on by the Office, or
    - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

- (c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:
  - (1) Each inventor named in the application:
  - (2) Each attorney or agent who prepares or prosecutes the application; and

- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.
- (d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.
- (e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby appoint the attorney(s) and/or patent agent(s) associated with the following customer number to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith.

23552
PATENT TRADEMARK OFFICE

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorncy/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant & Gould P.C. to the contrary.

I understand that the execution of this document, and the grant of a power of attorney, does not in itself establish an attorney-client relationship between the undersigned and the law firm Merchant & Gould P.C., or any of its attorneys.

Please direct all correspondence in this case to customer number 23552.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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